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EXHIBIT 5

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November 20, 2020

John J. Duffy
Swanson Martin & Bell, LLP
330 North Wabash Avenue
Suite 3300
Chicago, IL 60611

Re: Case No. 3:18-cv-01586-JSC

Dear Mr. Duffy,

You have retained me in the above referenced lawsuit. I prepared the following report summarizing my analysis and opinions in this matter and the bases thereof. Appendix A is a copy of my Curriculum Vitae and a list of my publications for the last ten years (and earlier). Appendices B, C, and D of this Report identify the case specific materials, reference materials, and data relied upon to form my opinions. I have not testified in any matter in the last four years.

The Complaint alleges that Plaintiffs sustained harm as a result of an incident in which a cryogenic storage tank, manufactured by Chart and located at Pacific Fertility, Pacific MSO, and Prelude's San Francisco facility, lost liquid nitrogen. The tank at issue ("Tank 4") is a Chart MVE 808AF-GB stainless steel freezer (Serial No. CAB2112020013). The claims against Chart include products liability, negligent failure to recall, failure to warn, manufacturing defect, and design defect.

SECTION I

SUMMARY OF BACKGROUND AND QUALIFICATIONS

I have an engineering background and expertise in cryogenic systems and pressure vessel design.¹ I am an Associate Professor in the Mechanical Engineering Department of the University of Wisconsin – Madison and the Chair of the Mechanical Engineering curriculum committee. I am a member of the American Society of Mechanical Engineering (ASME) and the Cryogenic Society of America (CSA). I serve on the boards of the Cryogenic Engineering Conference and the International Cryocooler Conference.

Prior to joining the faculty at the University of Wisconsin, I worked for NASA at the Goddard Space Flight Center. My work for NASA included the development of cryogenic thermal control systems for the James Webb Space Telescope, near absolute zero temperature cooling for astrophysics detectors, and thermal control systems for long-term space missions. I also served as

¹ Appendix A.

an expert on several design review panels for systems and missions, which involved review of designs for mission safety.

I completed my PhD research in the Cryogenic Engineering Laboratory at the Massachusetts Institute of Technology. Over the past 21 years, I have been involved in the design of several cryogenic systems. I have also conducted and directed research in the area of cryogenics.

Prior to starting the PhD program at MIT, I worked as the Director of Engineering at a small electric boiler and pressure vessel manufacturing company. My work included ASME boiler and pressure vessel design and boiler control systems designed to CSD-1 and UL 834.

SECTION II

SUMMARY OF FINDINGS AND OPINIONS

I offer all of my opinions in this report to a reasonable degree of engineering and scientific certainty. My opinions are based on my education, training, and experience in cryogenics and cryogenic product design, the manufacture and function of such products, my review and study of the information provided regarding the circumstances of this incident, my review and study of materials on the subject MVE 808AF-GB freezer, and the examination and testing of an exemplar.² My hourly rate is \$350.00 for work on this case.

It is my opinion that the subject tank, the MVE 808AF-GB freezer, was not defective or unreasonably dangerous in either design or manufacture. Any non-functional condition in the freezer did not cause any alleged damage to the tissue that forms the basis of Plaintiffs' complaint. It is also my opinion that Pacific Fertility employees caused the loss of liquid nitrogen cooling in the tank on March 4, 2018 through careless acts with respect to operation, procedure, and maintenance of the MVE 808AF-GB freezer ("Tank 4").

SECTION III

THE MVE 808AF-GB FREEZER WAS NOT

UNREASONABLY DANGEROUS IN ITS DESIGN

A. The MVE 808AF-GB

The MVE 808AF-GB is a cryopreservation freezer cooler by liquid nitrogen (LN2). The freezer is essentially a vacuum insulated tank (dewar) with space to immerse biological material in liquid nitrogen. The LN2 boils away as heat leaks into the cold space through the insulation system and through the top when the lid is opened to add or remove material from the tank. As the LN2 boils away, it is replenished by a control system that automatically opens a valve allowing LN2 to flow into the freezer from a LN2 supply dewar connected to the freezer by a piping system. A control system automatically maintains the LN2 level between low and high fill levels that the end user programs. The control system also has a low-level alarm that sounds when the LN2 level drops below a value set by the end user. Additionally, the control system calculates the rate of LN2 use, in units of inches per day, to allow the end user to monitor the performance of the freezer insulation system.

² Appendices A - C.

B. Fail-Safe Design

Engineers practice fail-safe design where, if you have a specific type of failure, the product inherently responds to cause minimal or no harm to other equipment or to people. When engineers design a system to be fail-safe, failure is neither impossible nor improbable. The system's design prevents or minimizes unsafe outcomes of its failure. Thus, if a portion of a fail-safe product fails, it remains at least as safe as it was before the failure.

C. Chart Employed a Fail-Safe Design for the MVE 808AF-GB.

Chart designed the MVE 808AF-GB as a dewar with a computer controller, the TEC 3000. The two worked together to keep samples at cryogenic temperatures. The dewar maintains temperature. The controller aided the dewar by monitoring liquid nitrogen ("LN2") level, temperature, LN2 usage, and other conditions.

The controller initiates a fill cycle when it observes conditions that are outside of the pre-programmed ranges for temperature and LN2 level. In a fill cycle, the solenoid valve opens to add LN2 to the dewar and maintain the temperature and LN2 level. The controller sounds an audible alarm if it observes the temperature rising, LN2 level falling, or LN2 usage increasing beyond desired levels. If the end user does not address the audible alarm, the controller signals a dialing device to notify the end user, via call or text, to check on the freezer and its samples.

The MVE 808AF-GB contained a fail-safe design to alarm and issue signals, including calling the end user, in the event of low LN2 level, an increase in LN2 usage, and/or a rise in temperature. The fail-safe design, thus, warned the end user to remedy the condition and protect the tank's samples.

D. Dr. Conaghan Disabled Chart's Fail-Safe Design, thereby misusing its Product.

Dr. Conaghan unplugged the MVE 808AF-GB on February 15, 2018.³ By unplugging the MVE 808AF-GB, Conaghan disabled three key components of the dewar's fail-safe design: filling, monitoring, and alarming. Pacific Fertility laboratory personnel admitted that, by unplugging the freezer, Dr. Conaghan transferred responsibility for filling and monitoring to human beings (specifically, the lab personnel), not the MVE 808AF-GB.⁴

E. Dr. Conaghan also misused the MVE 808AF-GB by Plugging in the Controller only to Initiate Fill Cycles.

Between February 15, 2018 and March 4, 2018, Dr. Conaghan also misused the MVE 808AF-GB by ordering his subordinates to plug in the controller in only to initiate a fill cycle. Dr. Conaghan's decision to operate the freezer without a working controller placed the tissue in Tank 4 at an increased risk of loss compared to tissue stored in tanks with fully operating controllers.

³ Conaghan Dep. (October 9, 2019), 79:15-20.

⁴ Conaghan Dep. (September 9, 2020), 157:13-19. Cirimele Dep. (August 31, 2020), 44:6-10. Fischer Dep., 264:11-25.

Specifically, unplugging the controller eliminated the following critical safety and fail-safe control capabilities:

1. Automatic Liquid Nitrogen Level Control

The controller monitored LN2 levels through pressure sensors in the dewar that relayed signals to the controller. If the LN2 level fell below the set low limit, the controller would signal the solenoid valve to open and allow LN2 to flow into the dewar, thereby raising the LN2 level and dropping the temperature.

2. Low Liquid Level and High Temperature Warnings and Alarms

Even if the automatic fill system stopped filling due to supply issues, alarms would have alerted staff that the level was low. Per Dr. Conaghan, the Tank 4 controller triggered the low-level audible alarm when the liquid level was sufficient and insufficient. Although an audible false low-level alarm may have been inconvenient to the laboratory personnel, it did not put the tissue in danger of exposure to high temperatures due to low LN2 levels. Dr. Conaghan disabled the low-liquid level alarm monitoring when he unplugged the controller and continued to operate Tank 4 without the device.

4. Lab Personnel Phone Notification System

Even if a full vacuum failure occurred in the middle of the night, the phone notification system known as “Sensaphone” would have alerted the lab personnel to low-level conditions with adequate time to transfer the Tank 4 tissue to the backup tank.

The manual safety protocol implemented by the laboratory was insufficient for two reasons:

- 1) Dr. Conaghan’s manual safety protocol was insufficient because it did not provide monitoring and alarm capabilities equivalent to those provided by a repaired or new controller. As a result, the safety of the tissue in Tank 4 was compromised.
- 2) Additionally, the manual monitoring protocol was not well implemented and monitored. Lab personnel admitted that not everyone manually measured LN2 levels and logged them into Reflections.⁵ Dr. Conaghan even admitted that his subordinates’ failure to measure and chart LN2 levels in Reflections (the software used to record LN2 measurements)

⁵ Cirimele Dep. (August 31, 2020), 76:17-23.

violated his lab's quality control policies.⁶ The poor implementation of laboratory protocol further compromised the safety of the tissue in Tank 4.

F. Dr. Conaghan should have repaired or replaced the controller. If he had done so, it is more likely than not that the controller would have alerted Dr. Conaghan and the lab personnel to the slow vacuum seal loss in the dewar, thereby preventing any damage to the samples.

As noted above, if the Pacific Fertility laboratory repaired or replaced the controller, the fail-safe features in Chart's design would have filled Tank 4 with LN2, alarmed when the temperature rose and/or LN2 level dropped, and called lab personnel if they failed to remedy the alarm conditions.

In 2011, Dr. Conaghan personally experienced a loss of vacuum seal in a dewar ("Tank 1") and the corresponding controller alarms.⁷ In that instance, as Tank 1 lost vacuum, the MVE controller continued to fill with LN2. As a result, Dr. Conaghan was able to preserve the samples by removing them from Tank 1 and placing them in a backup freezer.⁸ When asked about this incident, Dr. Conaghan provided the following testimony:

Q: "What tanks do you have a recollection of thawing out prior to the incident on March 4?"

A: "We had a tank failure back in 2011, and we thawed out that tank after we had removed its contents."⁹

Q: "How were you alerted about the issue with the problems with Tank 1 back in 2011?"

A: "We saw ice on the outside of the tank."

Q: "Anything else?"

A: "The auto fill for the tank was running continuously."¹⁰

Q: "What level [liquid nitrogen] was in there to your memory?"

A: "The level inside the tank was normal. I can't testify to how many inches were there?"

Q: "But it was not an abnormal level?"

A: "No."¹¹

Dr. Conaghan's testimony demonstrates his first-hand knowledge that a tank failure was a possibility. It also demonstrates his knowledge that the controller is key to saving samples in such a situation. The Tank 1 controller kept the tissue immersed in liquid nitrogen during the 2011 incident. Despite this knowledge, Dr. Conaghan failed to promptly repair and/or replace the Tank 4 controller. If he had replaced or serviced the controller, the autofill would have kept Tank 4 filled

⁶ Conaghan Dep. (September 9, 2020), 74:2-8.

⁷ Conaghan Dep. (September 9, 2020), 25:17-20; 26-28

⁸ Conaghan Dep. (September 9, 2020), 28:15-23

⁹ Conaghan Dep. (September 9, 2020), 25:17-20.

¹⁰ Conaghan Dep. (September 9, 2020), 26:3-7.

¹¹ Conaghan Dep. (September 9, 2020), 28:8-12.

on March 4, 2018, even if the LN2 usage rate was high. Additionally, at the time of the Tank 4 incident, Dr. Conaghan had a fully functional backup tank readily available at Pacific Fertility Center.¹² Yet, Dr. Conaghan still decided to use Tank 4 without a controller.

SECTION IV
CHART DID NOT MANUFACTURE AN
UNREASONABLY DANGEROUS MVE 808AF-GB

A. Pressure Vessel Design and Vacuum-Insulated Cryogenic Tank Design

I am very familiar with design to ASME boiler and pressure vessel code.¹³ I am also familiar with the requirements for quality management, including material certification, welder qualification, non-destructive evaluation, and the hydrostatic pressure testing that are required to manufacture and certify ASME vessels.¹⁴ The quality of an ASME stamped pressure vessel is verified by nondestructive evaluation of the welds and by hydrostatic proof testing. Pressure vessels are designed to withstand high pressure and have very high safety factors inherent in both the maximum allowable stress values for the material and the required wall thickness and weld dimension equations.

Vacuum vessels are not manufactured to conform to ASME code.¹⁵ Cryogenic vacuum insulated vessel designs are usually optimized to maximize thermal performance. This pushes the design toward thin wall materials with low thermal conductivity. Thin wall stainless steel or low conductivity composites such G10 fiberglass are often used. The thin stainless-steel neck and inner wall of the MVE 808AF-GB is an example of good cryogenic vessel design. Additionally, because the walls of the vessel are very thin, the welds are typically designed to be seal welds. The measure of quality for vacuum vessel construction including welds is the helium leak rate. The instrument used to verify the integrity of the vacuum vessel as manufactured is the helium mass spectrometer leak detector. If the welds of a vacuum insulated cryogenic tank pass a mass spectrometer leak test, they are considered to be good welds.

[REDACTED]

[REDACTED]

¹² Conaghan Dep. (September 9, 2020), 18:17-19.

¹³ See Appendix A. I worked for four years as a design engineer and director of engineering at an electric boiler and pressure vessel manufacturer after finishing my MS in Mechanical Engineering. I continued to work for that company as a consultant until 2017. I consulted on issues related to ASME code compliance and pressure vessel design.

¹⁴ See Footnote 13.

¹⁵ Since completing my Ph.D., I have designed and procured several vacuum insulated cryogenic vessels both at NASA and at the University of Wisconsin – Madison.

¹⁶ See Footnote 15.



C. Pacific Fertility Expert Spoliation of Evidence

In March of 2018, Pacific Fertility experts from Exponent inspected the freezer.²² Pacific Fertility neither advised nor invited to the inspection the patients or Chart and their experts.²³ The methods used during the testing irreversibly altered the condition of Tank 4 and prevented a determination of its condition prior to the incident on March 4, 2018.²⁴

During this inspection, Exponent engineers sprayed a substance on the subject dewar to run a leak rate test.²⁵ That spray plugged any small leaks that may have existed in the dewar and prevented me from running a more accurate leak rate test that likely would have uncovered the areas where the slow leak was in the subject dewar. Additionally, as part of the testing, the fill port cap with an O-ring was removed before the leak rate test.²⁶ This prevented me from evaluating whether a leak existed at the O-ring and plug for the fill port.

D. The MVE 808AF-GB Was Out of Warranty

Cryogenic dewars use seal welds and have a fill port with an O- ring usually made of a polymer. Over time, dewars vacuum seal degrades. Chart required end users to check the dewar for ice build up and if it impaired the ability of the user to access and retrieve samples, to thaw the freezer. (Chart Cryogenic Freezer with MVE TEC 3000 Controllers Technical Manual, p. 114.) (“Check freezer at a 5 year interval and thaw only if ice builds up enough to impede the proper insertion, access, and retrieval of samples, and/or the ice effects accurate liquid level reading.”).²⁷

¹⁷ Ingram Dep., 33:11-22. Ingram Dep. Ex. 666, Bates No. CHART070444.

¹⁸ See Chart’s Answers to Plaintiffs Requests for Admission Set 4. See also, Chart’s Answers to Plaintiffs’ Interrogatories Set 6.

¹⁹ Ingram Dep., 35:22-36:5.

²⁰ Ingram Dep., 50:15-19. Eubanks Dep., 42:9-13.

²¹ Ingram Dep., 32:9-13.

²² See Chart’s Answers to Plaintiffs’ Requests for Admission Set 4. See also, Chart Answers to Plaintiffs’ Interrogatories Set 6.

²³ Id.

²⁴ Id.

²⁵ Id.

²⁶ Kasbekar Dep., 103:12-15; 109:9-110:1.

²⁷ Chart Cryogenic Freezer with MVE TEC 3000 Controller Technical Manual, Preventative Maintenance Schedule, pg. 114.

At the University of Wisconsin, I instruct my graduate students to check the dewars they use for signs of vacuum seal loss. If a vacuum seal is degrading, they can revac the dewar connecting a vacuum manifold to the pump-out port and pumping on the vacuum space while blowing warm air inside the dewar to drive contaminants from the getter material. A high vacuum gauge monitors the pressure in the vacuum space during the process. The process takes several hours. Once the revac process is complete, a helium mass spectrometer leak detector is used to test the integrity of the vacuum. After vacuum integrity is verified, the pump-out port is resealed and the vacuum manifold is removed.

Chart MVE dewars are under warranty for five years.²⁸ The subject MVE 808AF-GB was sold to Pacific Fertility in 2011.²⁹ At the time of the incident in March 4, 2018, the dewar was out of warranty.

SECTION V

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SECTION VI EXEMPLAR TANK TESTING

As set forth below, my testing disproved Dr. Kasbekar's conclusions that the MVE 808AF-GB lost vacuum seal rapidly. It also disproved Jean Popwell's LN2 measurement of 14 inches on March 3, 2018.

²⁸ Bies Dep. (September 18, 2019), 104. Bies Dep. Ex. 38, MVE Cryo Preservation for Life Science, Storage & Transport Systems for MVE Cryopreservation, pg. 11 ("TWO years parts warranty – FIVE years vacuum warranty").

²⁹ Conaghan Dep. (October 9, 2019), 64:2.

³⁰ Kasbekar Dep. Ex. 3, Chart Recall Notice.

A. Events Before and On March 4, 2018

During his December 13, 2019 deposition, the plaintiffs' expert, Dr. Kasbekar, asserted that twenty to thirty liters of nitrogen in liquid form entered the vacuum space during the event.³¹ The 1.189 kg of zeolite type molecular sieve removed from Tank 4 during the March 11, 2020³² inspection has the capacity to hold approximately 0.2 kg of nitrogen when cooled to approximately -196 degrees C (77.2 Kelvin). (*Yang and Burris paper*). This corresponds to 175 liters of nitrogen gas at standard conditions (atmospheric pressure and room temperature). 0.2 kg of nitrogen is approximately 0.25 liters of nitrogen in liquid state.³³ Liquid nitrogen at atmospheric pressure entering a vacuum through a small hole or crack would immediately flash to vapor due to the reduced pressure. This gas would expand by a factor of 700 as it became warm when interacting with the warm outer walls of the tank and the warm layers of the 30-layer insulation blanket.³⁴ This would cause the pressure in the vacuum space to rise to atmospheric pressure and stop the liquid flow from the tank into the vacuum space long before even one liter of liquid nitrogen could flow into the vacuum space.

It is my opinion that the following sequence of events led to the loss of liquid nitrogen and the "implosion" of the inner wall of Tank 4:

- 1) On February 15, 2018, the TEC 3000 controller on Tank 4 alarmed indicating a zero liquid nitrogen level when the tank was not at zero level. The lab personnel were not able to reset the controller or eliminate the alarm condition. Consequently, Dr. Conaghan decided to disconnect the power to the controller and implement a procedure for manual level monitoring and manual liquid nitrogen fill rather than have the freezer serviced or move the tissue to a backup freezer.
- 2) Tank 4 at some point had developed a small leak into the vacuum space that was slow enough to be managed by the adsorption capacity of the molecular sieve. This is supported by testimony from Dr. Conaghan's testimony that there was no report from anyone in the lab that there was visible condensation on Tank 4 or ice around the lid during normal operation before or on March 3, 2018 or on the morning of March 4, 2018.³⁵ Tank wall condensation and icing, and icing around the perimeter of the tank lid are indicative of full vacuum failure as demonstrated by exemplar MVE 808AF-GB tank testing outlined later in this report.
- 3) This slow leak led to molecular sieve loading with gas over time. This could have happened over several days or even weeks.
- 4) The tank ran out of liquid Nitrogen on March 4, 2018. This is supported by Dr. Conaghan's testimony that there was one inch of frost on the dipstick when he attempted to measure

³¹ Kasbekar Dep., 24:2-4.

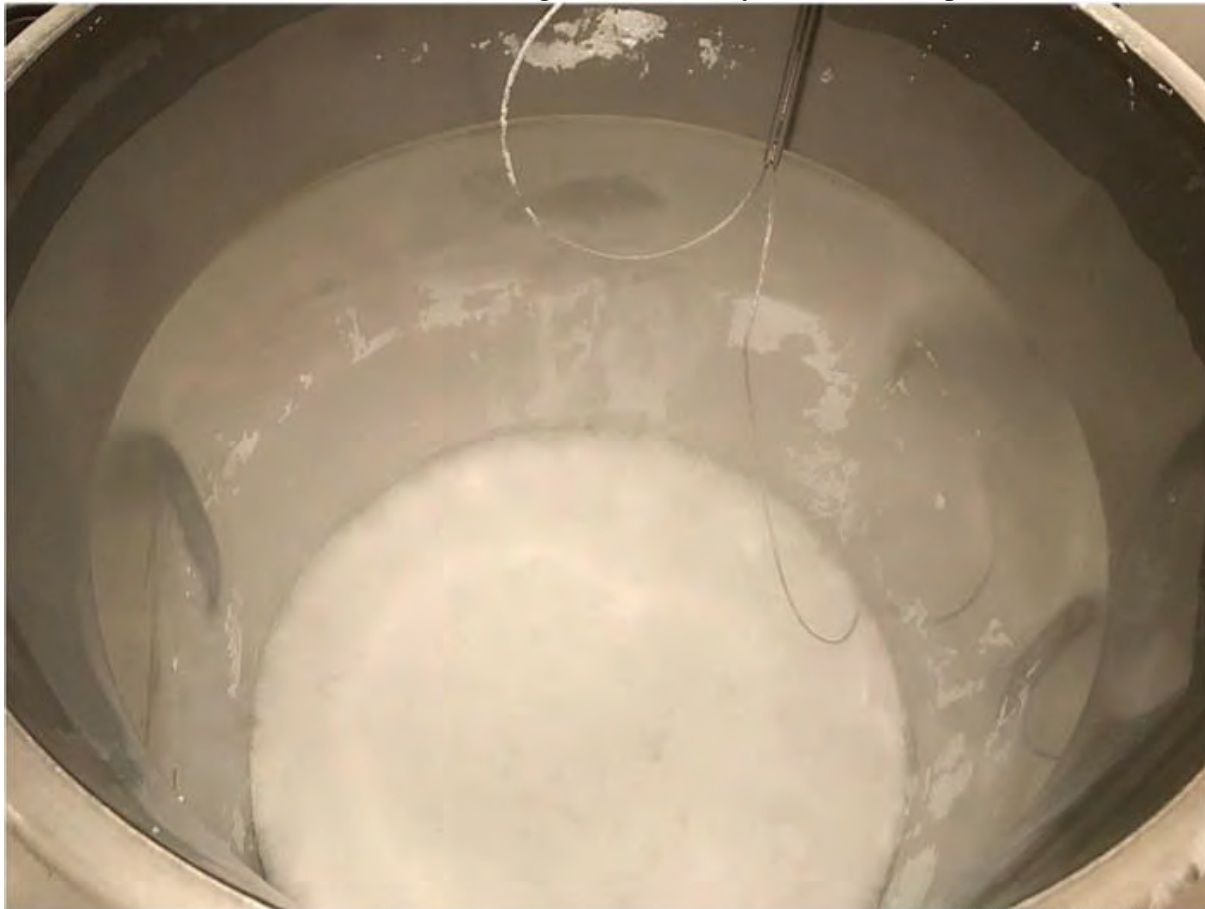
³² Brand Field Notes, March 11, 2020.

³³ Appendix C, Calculations.

³⁴ Brooks Dep. (January 23, 2020), 29:2-6.

³⁵ Conaghan Dep. (September 9, 2020), 212:19; 213: 1-2). Conaghan Dep. (October 9, 2019), 115:20-22; 135:21-24; 136:8-9.

the liquid level even after the autofill was on for a few minutes.³⁶ This frost indication could have been from the liquid just added to the tank or from the layer of ice at the bottom of the tank mentioned in Dr. Conaghan's testimony and visible in pictures of the tank.³⁷



March 4, 2018, 4:44 PM

Figure 1. Photograph of Tank 4 after tissue was removed on March 4, 2018 with ice visible on the bottom of the tank.

- 5) The molecular sieve released gas into the vacuum space as it warmed. My calculations indicate that the molecular sieve has the capacity to hold enough Nitrogen at -196°C such that the pressure in the vacuum space will exceed 1.74 atmospheres (0.74 atmosphere or 10.86 psi above ambient pressure) when the tank is warmed to room temperature. The partial release of this gas when the tank began to warm caused increased heat conduction across the vacuum space to the bottom of the inner tank which was still cold because the cold boxes and samples were sitting on the bottom of the tank. This is consistent with Dr. Conaghan's testimony, and those of his lab personnel colleagues, that there was no condensation on the walls of the tank but some water under the tank indicating condensation on the bottom of the tank.³⁸

³⁶ Conaghan Dep. (September 9, 2020), 208:16.

³⁷ Conaghan Dep. (September 9, 2020), 206:17-22; 207:15-208:2. Conaghan Dep. (October 9, 2019), 113:12-24.

³⁸ Conaghan Dep. (September 9, 2020), 165:13-14. Conaghan Dep. (October 9, 2019), 115:20-22; 135:21-24; 136:8-9. Popwell Dep., 72:4-5. Han Dep., 19:10-12.

- 6) The rising pressure in the vacuum space caused the neck to begin to deform and squeeze the foam neck plug on the lid making the lid difficult to remove when Dr. Conaghan tried to open the freezer at 12:20 pm on March 4, 2018.³⁹

When lab personnel filled the tank with LN2 this reduced the pressure in the vacuum space as the molecular sieve began to cool and partially re-adsorb the gas. This halted deformation of the inner wall of the tank.

It is important to note that once some of the gas was released and the molecular sieve was no longer cold, the sieve would not be able to re-adsorb all of the released gas and full vacuum could not be restored without pumping the system and regenerating the sieve. At this point the integrity of the vacuum insulation could not be restored by filling the tank with liquid Nitrogen.



Figure 2. Photograph of Tank 4 on March 4, 2018 showing partial deformation of the tank neck.

³⁹ Conaghan Dep. (October 9, 2019), 40:15-22.

- 7) Once tissue was transferred and the liquid completely boiled away, the molecular sieve warmed thereby releasing all of the absorbed gas. The pressure in the vacuum space rose well above the bucking pressure limit for the tank neck and the entire tank “imploded.”

My calculations show that the pressure required to completely buckle the thin wall neck of the tank is less than 6.3 psi above atmospheric pressure. The main cylindrical part of the inner wall is thicker and would require less than 7.2 psi above atmospheric pressure to buckle. The 1.74-atmosphere absolute pressure (0.74 atmosphere or 10.86 psi gauge pressure) resulting from the release of gas from the molecular sieve was more than enough to buckle both the neck and the main inner wall of the tank.

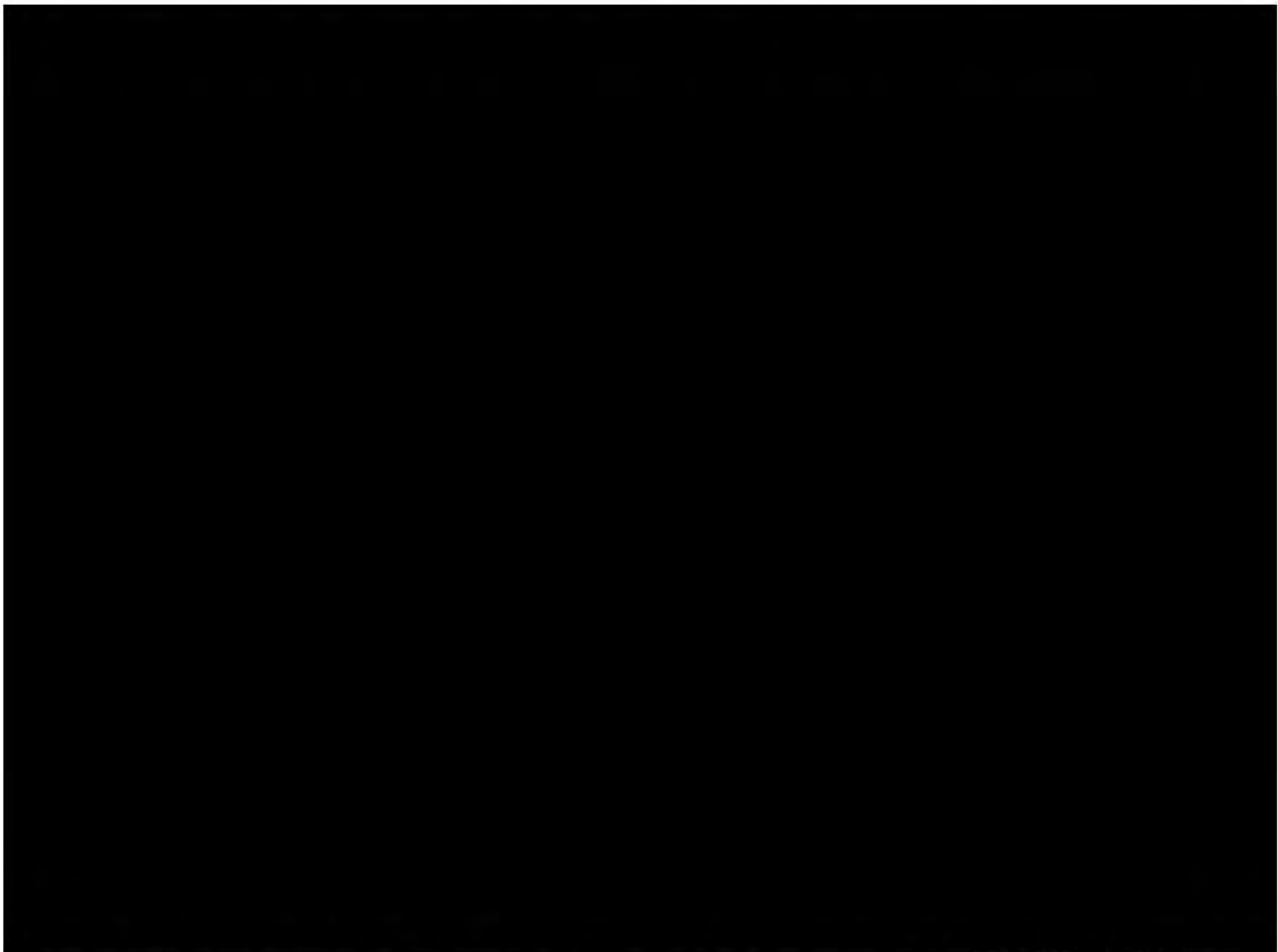


Figure 3. Photograph of Tank 4 on March 6, 2018 showing result of implosion/buckling due to gas released from the sieve as it warmed to room temperature.

[REDACTED]

[REDACTED]

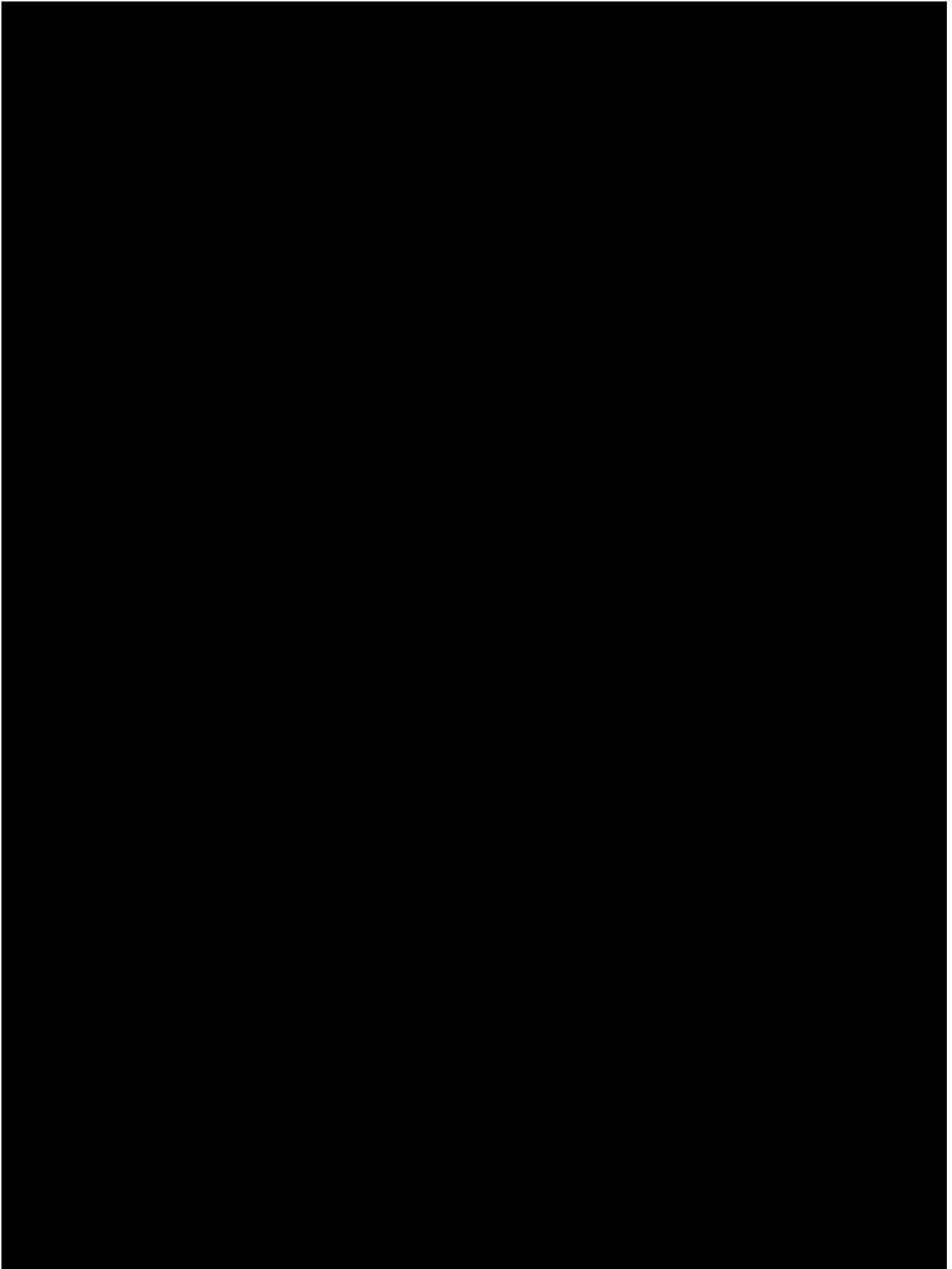
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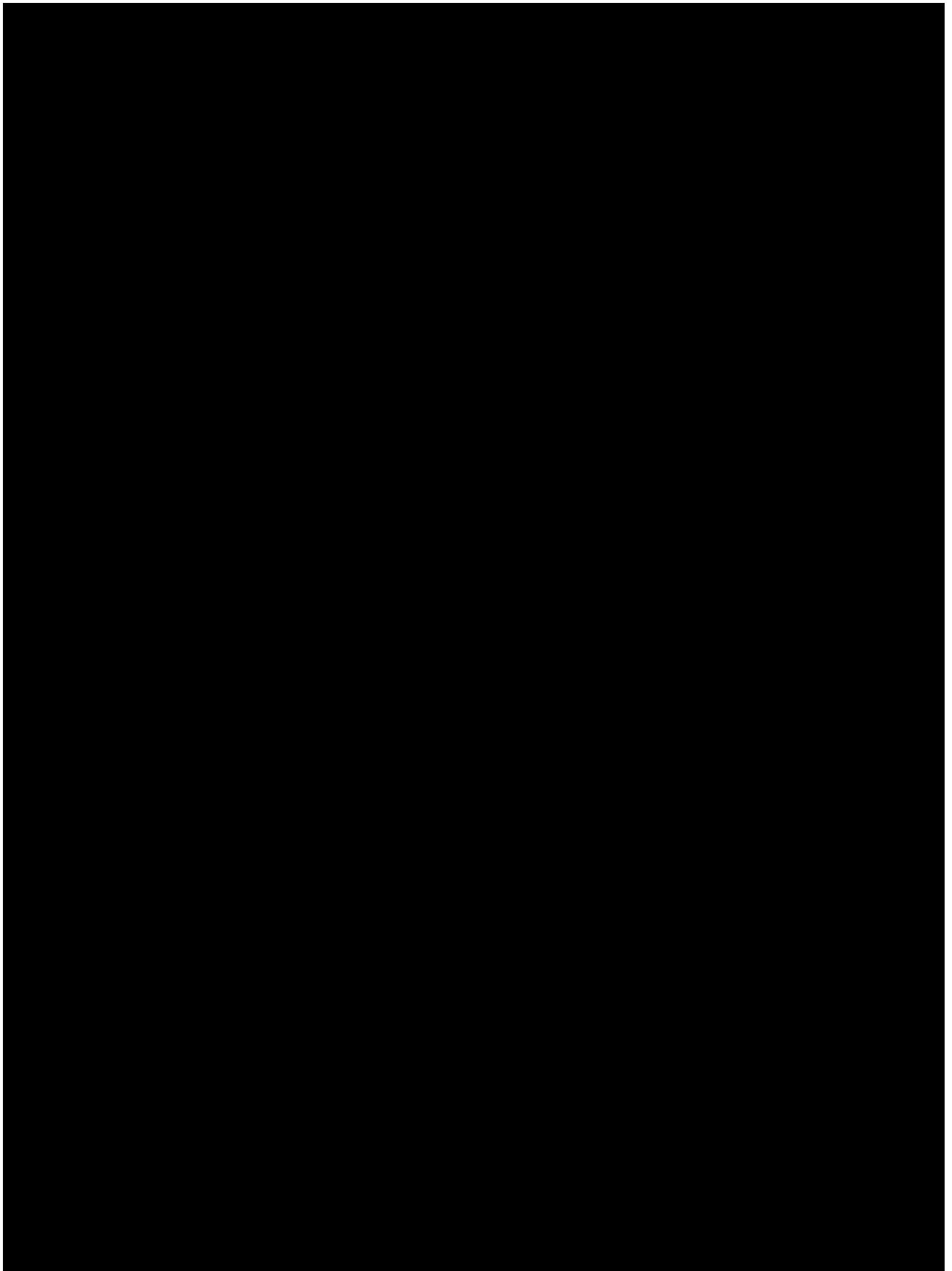
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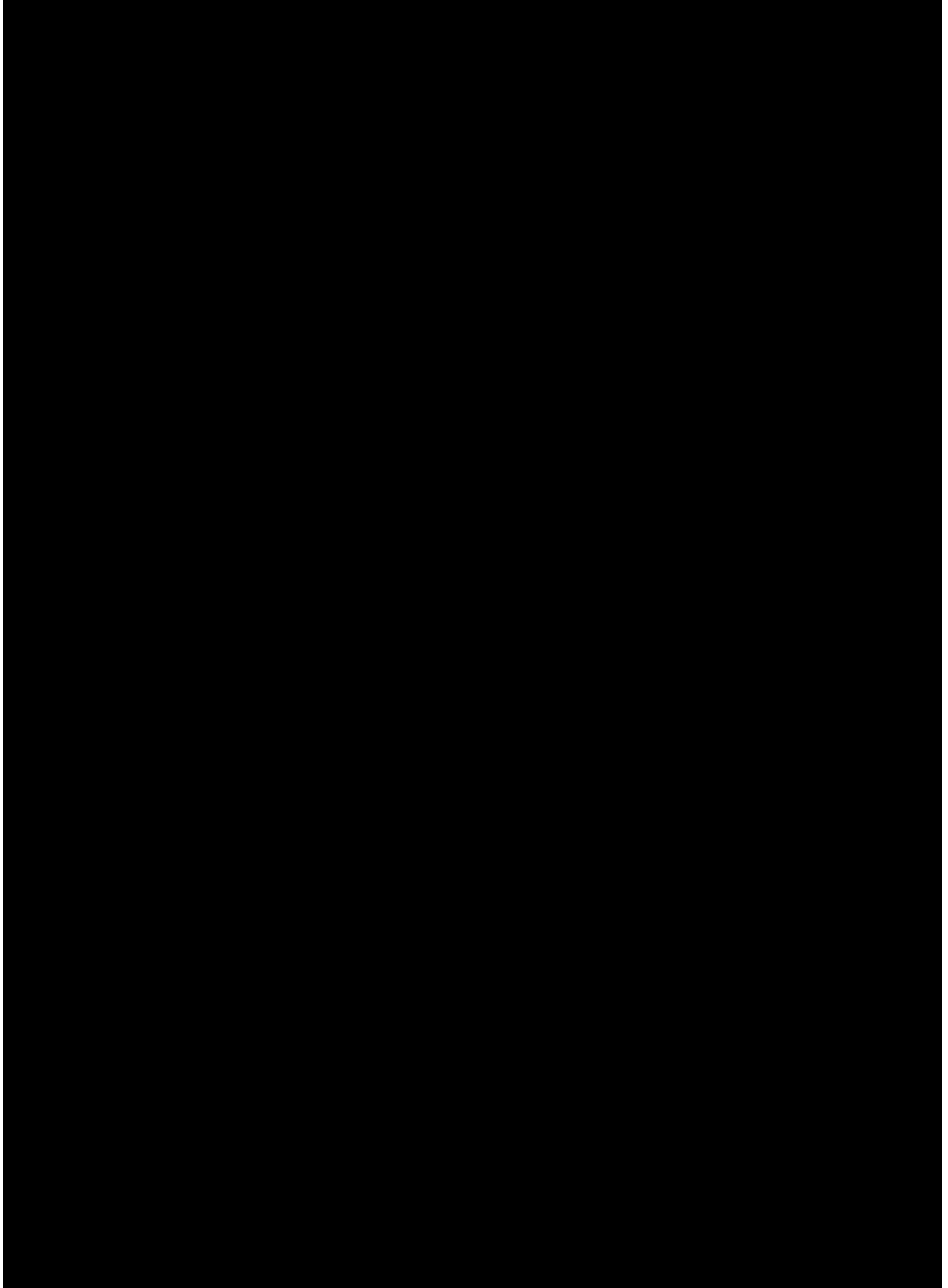
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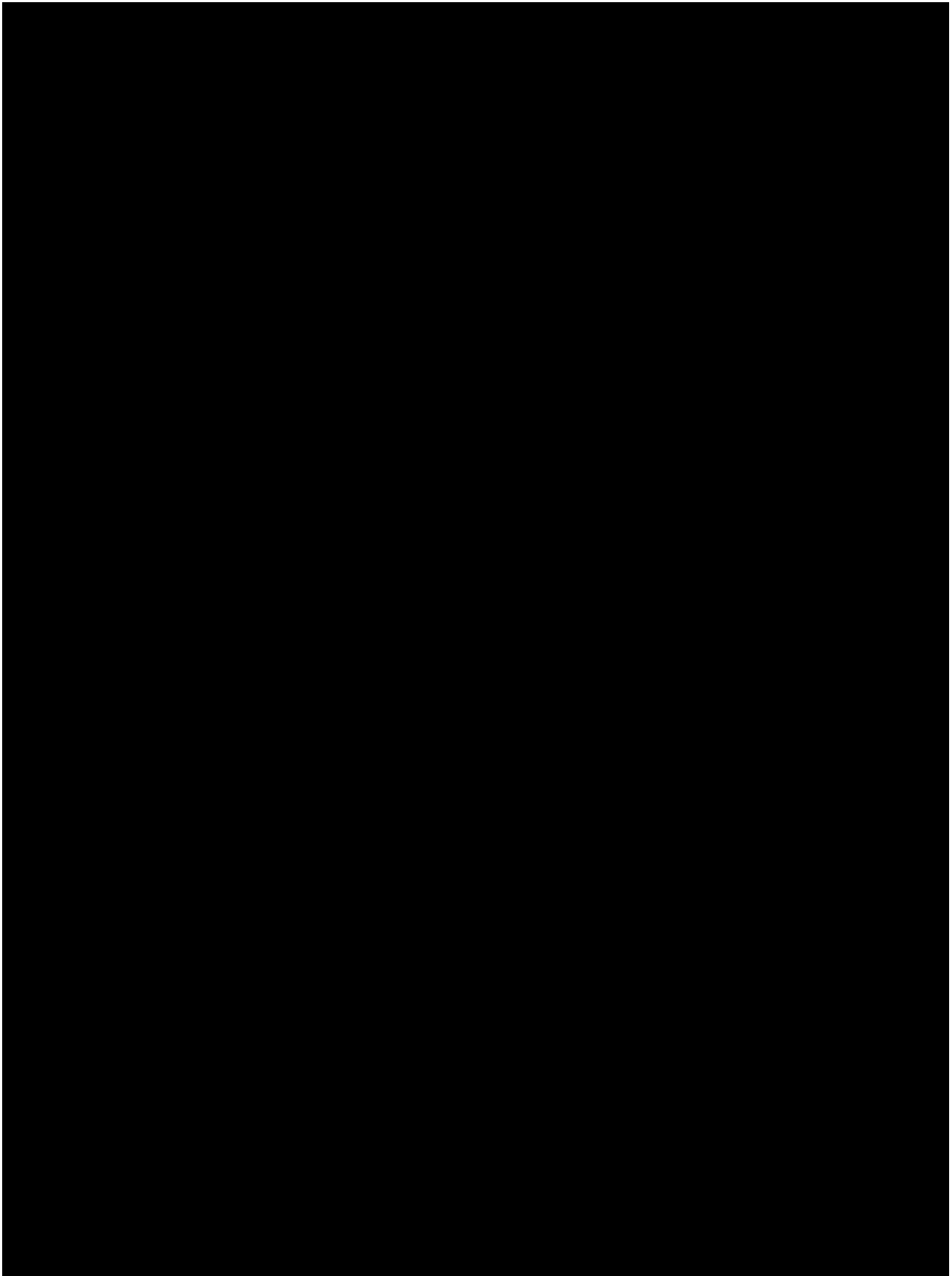


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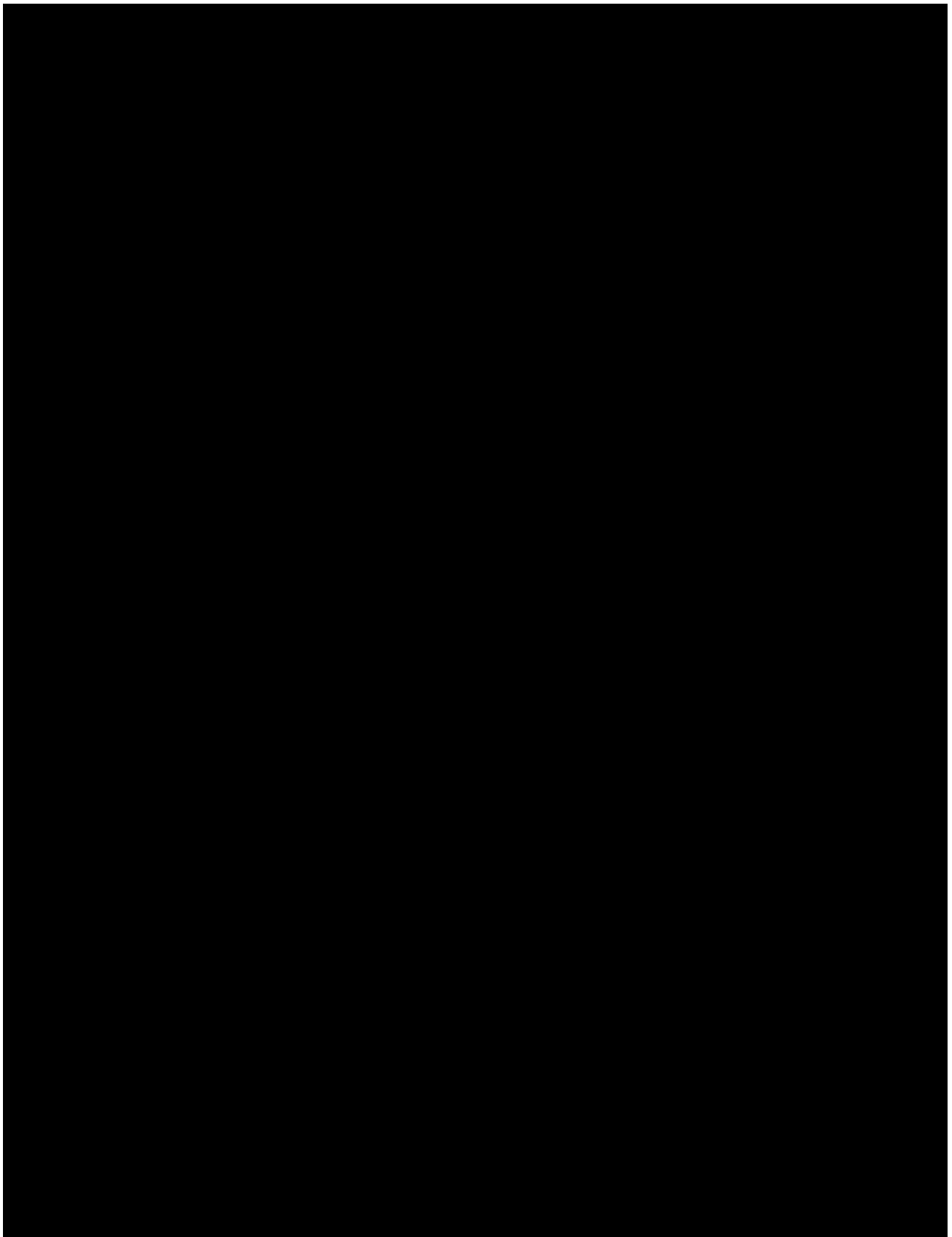




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[REDACTED]

[REDACTED]



⁵⁰ CHART070093-070127.

explanation for low liquid level events when the controller was operational. The Pacific Fertility lab assistants had the responsibility of ordering LN2 supply for the laboratory.⁵¹ Prior to the incident, the lab assistants did not calculate LN2 consumption.⁵² Instead, the lab assistants merely shook the supply tank to gauge whether it was empty or full.⁵³ The LN2 supply can was empty on at least four or five occasions.⁵⁴

Although I could not determine the liquid levels in Tank 4 after the controller was disconnected from power on February 15, 2018, I could estimate the daily fill times from the event log because it was connected intermittently to enable the autofill feature. The fill times on five of the six days leading up to the March 4, 2018 event were much longer than historical values. It is likely that there was an insufficient supply of liquid nitrogen to fill Tank 4 in the days leading up to the March 4, 2018 event.

When the supply tanks connected to the Tank 4 piping system ran out of LN2, they would need to be replaced with full supply tanks by Pacific Fertility lab staff. Dr. Conaghan testified that this is not a designated task.⁵⁵

Despite the fact that the fill times were unusually long for Tank 4 on five of the six days leading up to the March 4, 2018, Dr. Conaghan and the rest of the Pacific Fertility lab staff did not do an investigation into the supply of LN2 or verify that the supply tanks connected to Tank 4 were sufficiently full.⁵⁶

SECTION VIII



⁵¹ Lamb Dep., 42:3.

⁵² Lamb Dep., 42:25.

⁵³ Lamb Dep., 43:8-12.

⁵⁴ Lamb Dep., 48:9-10.

⁵⁵ Conaghan Dep. (November 13, 2020), 30:25.

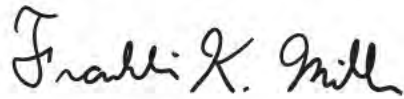
⁵⁶ Conaghan Dep. (November 13, 2020), 31:15-22; 35:14-20.

SECTION IX
SUMMARY OF FINDINGS

1. When properly maintained and operated, the MVE 808AF-GB freezer is safe in its design and manufacture for all reasonably foreseeable uses. The MVE 808AF-GB freezer does not possess any design or manufacturing defects. No design or manufacturing defects existed in its condition and functionality that resulted in the loss of any tissue and the MVE 808AF-GB freezer did not possess any defective or unreasonably dangerous conditions that caused the loss of tissue.
2. When Dr. Conaghan unplugged the MVE 808AF-GB on February 15, 2018, he disabled Chart's fail-safe design, thereby misusing its product. Between February 15, 2018 and March 4, 2018, Dr. Conaghan also misused the MVE 808AF-GB by ordering his subordinates to plug it in briefly only to initiate a fill cycle.
3. Dr. Conaghan should have repaired or replaced the controller and, had he done so, it is more likely than not, the controller would have alerted to the slow vacuum seal loss in the dewar, thereby preventing any damage to the samples.
4. Chart did not manufacture an unreasonably dangerous MVE 808AF-GB. The seal welds used in the MVE 808AF-GB dewar were reasonably safe.
5. The subject MVE 808AF-GB was slowly losing vacuum seal, however, Pacific Fertility experts spoliated the evidence during the unilateral March 2018 inspection and test, thereby precluding my ability to determine the precise location where the vacuum seal gave way on March 4, 2018.
6. Vacuum-insulated cryogenic tanks lose vacuum seal over time. The subject MVE 808AF-GB was out of warranty at the time of the incident.
7. Chart's freezer recall does not apply to the subject MVE 808AF-GB. The recalled freezers are not substantially similar to the MVE 808AF-GB in material or design.
8. My testing disproved Dr. Kasbekar's conclusions that the MVE 808AF-GB lost vacuum seal rapidly. My testing also disproved Jean Popwell's LN2 measurement of 14 inches on March 3, 2018.
9. Tank 4 has a history of low-level events and long fill times prior to February 15, 2018. In some instances, the Tank 4 auto fill only delivered approximately one inch of liquid nitrogen in one hour. On five of the six days leading up to the March 4, 2018 event, the fill times were much longer than historical values. Long fill times tend to prove that there is an insufficient supply of liquid nitrogen in the supply Dewar.

I reserve the right to change and supplement my opinions and conclusions following my examination of any additional case materials presented, including deposition transcripts.

Respectfully Submitted,

A handwritten signature in black ink that reads "Franklin K. Miller". The signature is written in a cursive, slightly slanted style.

Franklin K. Miller

Appendix A: Curriculum Vitae for Franklin K. Miller, PhD

Education

B.S. in Mechanical Engineering, West Virginia University, December 1991

M.S. in Mechanical Engineering, West Virginia University, August 1995

Ph.D. in Mechanical Engineering, Minor in Physics, Massachusetts Institute of Technology, February 2005

Thesis: The Development of a Superfluid Joule-Thomson Refrigerator for Cooling below 1 Kelvin

Professional Society Membership and Board Membership

American Society of Mechanical Engineering

Cryogenic Society of America

International Cryocoolers Conference Board

Cryogenics Engineering Conference Board

Professional/Research Experience

2017 – Present	Associate Professor , University of Wisconsin-Madison
2009-2016	Assistant Professor , University of Wisconsin-Madison
2004-2009	Cryogenic Engineer , NASA Goddard Space Flight Center Development of spaceflight cryogenic systems including systems for the James Webb Space Telescope
1999- 2004	Graduate Research Assistant , Massachusetts Inst. of Technology
1994-1998	Director of Engineering , Reimers Electra Steam, Inc. Responsible for design of pressure vessels and miniature steam boilers.

Honors and Awards

Best paper award in *Cryogenics* journal, 2014

Best paper award in *Cryogenics* journal, 2007.

Invited Talks

Invited seminar presentation at Chinese Academy of Sciences, Beijing, China, May 2019
“Progress on Cryogenic Pulsating Heat Pipes at the University of Wisconsin”

Invited seminar presentation at Chinese Academy of Sciences, Beijing, China, May 2019
“Adiabatic Demagnetization Refrigeration for Space Science Applications”

Invited seminar presentation at Zhejiang University, Hangzhou, China, June 2018
“Progress in Cryogenic Research at the University of Wisconsin”

Invited seminar presentation at Purdue University, January 2016.
“*Novel Sub-Kelvin Cooling Techniques for Space Science Applications*”

Invited seminar presentation at Georgia Institute of Technology, September 2015.
“*Novel Sub-Kelvin Cooling Techniques for Space Science Applications*”

Invited seminar presentation at Florida State University, September 2015.
“*Novel Sub-Kelvin Cooling Techniques for Space Science Applications*”

Invited seminar presentation at Duke University, April 2015.
“*Novel Sub-Kelvin Cooling Techniques for Space Science Applications*”

Invited talk at the AIAA Aerospace Sciences Meeting, January 2011.
“*Development of a Numerical Model for a Superfluid Magnetic Pump for Space Applications*”

Invited seminar presentation at Tufts University, November 2010.
“*Novel Sub-Kelvin Cooling Techniques for Space Science Applications*”

Peer Reviewed Publications

E Sheehan, J Pfothauer, F Miller, “Development of a high-effectiveness slotted plate cryogenic heat exchanger”, *IOP Conference Series: Materials Science and Engineering* 755 (1), 012030 (2020).

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E Sheehan, J Pfotenhauer, F Miller, O Christianson, “Quench Detection and Protection of an HTS Coil”, *IOP Conference Series: Materials Science and Engineering* 278 (1), 012182 (2017).

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Z Yu, F Miller, JM Pfotenhauer, “Numerical modeling and analytical modeling of cryogenic carbon capture in a de-sublimating heat exchanger”, *IOP Conference Series: Materials Science and Engineering* 278 (1), 012032, (2017)

X Zhi, JM Pfotenhauer, F Miller, V Gershtein, “Numerical study on the working performance of a GM cryocooler with a mechanically driven displacer”, *International Journal of Heat and Mass Transfer* 115, 611-618, 2017

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Appendix B: Case Specific Materials Relied Upon

1. Videos, photos and documents from September 6, 2019, September 30 - October 1, 2019, and March 11-13, 2020 inspections.
2. Transcript of Joseph Conaghan's deposition and accompanying exhibits from 10/9/2019
3. Transcript of Joseph Conaghan's deposition and accompanying exhibits from 9/9/2020
4. Transcript of Erin Fischer's deposition and accompanying exhibits
5. Transcript of Gina Cirimele's deposition and accompanying exhibits
6. Transcript of Hana Lamb's deposition and accompanying exhibits
7. Transcript of Jean Popwell's deposition and accompanying exhibits
8. Transcript of Jeff Brooks' deposition and accompanying exhibits
9. Transcript of Ramon Gonzalez's deposition and accompanying exhibits
10. Transcript of Justin Junnier's deposition and accompanying exhibits
11. Transcript of Brendon Wade's deposition and accompanying exhibits
12. Transcript of Jeffery Dresow's deposition and accompanying exhibits
13. Transcript of Frank Bies' deposition and accompanying exhibits
14. Transcript of Arun Sharma's deposition and accompanying exhibits
15. Transcript of Gregory Mueller's deposition and accompanying exhibits
16. Transcript of William Pickell's deposition and accompanying exhibits
17. Expert Report from Anand Kasbekar
18. Transcript of Anand Kasbekar's deposition and accompanying exhibits
19. Expert Report from Christopher Brand
20. Transcript of Christopher Brand's deposition and accompanying exhibits
21. Christopher Brand File Materials and Notes
22. Expert Report from Keith Gustafson
23. Transcript of Keith Gustafson's depositions and accompanying exhibits
24. Expert Report from Stephen Somkuti
25. Expert Report from Heather Huddleston
26. Expert Report from Nicholas Jewell
27. Expert Report from Duane Steffey
28. Expert Report from Shuanggee Ma
29. CHART Recall Notice (CHART000001-6)
30. Chart Drawings (PROD003) (CHART000061 – CHART000126)
31. Spreadsheet – Event Log, 10-18-2019
32. Spreadsheet – Maximum Event Log, 10-18-2019
33. Data download from MVE TEC 3000 on Tank during full vacuum failure test Oct. 26-29, 2020
34. Complaint
35. Exemplar MVE 808AF-GB
36. Chart's Answers to Plaintiffs' Interrogatories (Set 6)
37. Chart's Answers to Plaintiffs' Requests to Admit (Set 4).

The exhibits I may use to explain or support the opinions expressed at trial include the aforementioned materials along with exemplar dewars, controllers, and liquid nitrogen, and other demonstrative exhibits.

Appendix C: References

1. L.C. Yang, T.D. Vo, H.H. Burris, “Nitrogen adsorption isotherms for zeolite and activated carbon”, *Cryogenics*, December 1982 pp. 625-634
2. P.J. Sun, J.Y. Wu, P. Zhang, L. Xu, M.L. Jiang, “Experimental study of the influences of degraded vacuum on multilayer insulation blankets”, *Cryogenics*, 49, pp.719-726, (2009)
3. G.L. Mills, C.M. Zeller, “The performance of gas filled multilayer insulation”, *Advances in Cryogenic Engineering*, CEC Vol. 53 AIP (2008)
4. J.R. Feller and W.L. Johnson “Dependence of multilayer insulation thermal performance on interstitial gas pressure”, *Advances in Cryogenic Engineering*, AIR Conf. Proc. (2012)
5. Amir A. Srag, A.M.A. El-Butchand, Tanner Elsayed, “Buckling of thin walled long steel pipes subjected to external pressure in process industries”, *International Journal of Innovative Science, Engineering & Technology*, Vol. 2 Issue 12 pp 434-444, December 2015

Appendix D: Calculations*Pressure in vacuum space due to gas desorbed from molecular sieve as Tank 4 warmed*

$$m_{\text{sieve}} = 1.1888 \text{ [kg]} \text{ Mass of molecular sieve removed from Tank 4 from inspection notes}$$

$$m_{\text{N2,per,m,sieve}} = 0.167 \text{ [kg/kg]} \text{ Sieve capacity for N2 at 78.92 Kelvin kg N2 per kg sieve from Yang and Burris paper}$$

$$m_{\text{N2}} = m_{\text{N2,per,m,sieve}} \cdot m_{\text{sieve}} \text{ Mass of N2 adsorbed in the sieve at 78.92 K}$$

$$T = 300 \text{ [K]} \text{ Room Temperature}$$

$$V_{\text{vac}} = 100.3 \text{ [l]} \cdot \left| 0.001 \cdot \frac{\text{m}^3}{\text{l}} \right| \text{ Volume of the vacuum space in the MVE 808 Tank}$$

$$v_{\text{sp}} = \frac{V_{\text{vac}}}{m_{\text{N2}}} \text{ Specific volume of N2 in the vacuum space after it desorbs from the sieve}$$

$$P = P \text{ (Nitrogen , } T = T, v = v_{\text{sp}} \text{) } \text{ Absolute pressure in the vacuum space once the sieve warms}$$

$$P_{\text{gauge}} = (P - 101325 \text{ [Pa]}) \cdot \left| 0.000145038 \cdot \frac{\text{psi}}{\text{Pa}} \right|$$

$$P_{\text{atm}} = 101325 \text{ [Pa]} \text{ Atmospheric Pressure}$$

$$v_{\text{sp,gas}} = v \text{ (Nitrogen , } T = T, P = P_{\text{atm}} \text{) } \text{ Specific volume of N2 at STP}$$

$$v_{\text{sp,liq}} = v \text{ (Nitrogen , } P = P_{\text{atm}} , x = 0 \text{) } \text{ Specific volume of LN2 at 77.2 K}$$

$$\text{Ratio} = \frac{v_{\text{sp,gas}}}{v_{\text{sp,liq}}} \text{ Ratio of volume of N2 gas at STP to volume of LN2 at 77.2 K}$$

SOLUTION**Unit Settings: SI K Pa J mass deg**

$$m_{\text{N2}} = 0.1985 \text{ [kg]}$$

$$m_{\text{sieve}} = 1.189 \text{ [kg]}$$

$$P_{\text{atm}} = 101325 \text{ [Pa]}$$

$$\text{Ratio} = 708.2$$

$$v_{\text{sp}} = 0.5052 \text{ [m}^3\text{/kg]}$$

$$v_{\text{sp,liq}} = 0.001241 \text{ [m}^3\text{/kg]}$$

$$m_{\text{N2,per,m,sieve}} = 0.167 \text{ [kg/kg]}$$

$$P = 176189 \text{ [Pa]}$$

$$P_{\text{gauge}} = 10.86 \text{ [psi]}$$

$$T = 300 \text{ [K]}$$

$$v_{\text{sp,gas}} = 0.8786 \text{ [m}^3\text{/kg]}$$

$$V_{\text{vac}} = 0.1003 \text{ [m}^3\text{]}$$

No unit problems were detected.

KEY VARIABLES

$$P_{\text{gauge}} = 10.86 \text{ [psi]} \text{ Pressure in vacuum space in excess of atmospheric pressure. This is more than enough to buckle the inner tank wall.}$$

Buckling Calculations for Inner Neck of MVE 808 Freezer

$$D = 25 \text{ [in]} \cdot \left| 0.0254 \cdot \frac{\text{m}}{\text{in}} \right| \text{ Diameter of inner neck wall}$$

$$L = 8 \text{ [in]} \cdot \left| 0.0254 \cdot \frac{\text{m}}{\text{in}} \right| \text{ Length of neck}$$

$$t_w = 0.023 \text{ [in]} \cdot \left| 0.0254 \cdot \frac{\text{m}}{\text{in}} \right| \text{ Inner Neck Wall Thickness Dimension From Christopher Brand's Field notes 9/6/19 inspection}$$

$$R = \frac{D}{2} \text{ Radius is 1/2 Diameter}$$

$$T = 290 \text{ [K]}$$

$$E = \text{YoungsModulus} (\text{Stainless}_{\text{AISI304}}, T = T) \text{ Young's Modulus for 304 Stainless}$$

$$\nu = \text{PoissonsRatio} (\text{Stainless}_{\text{AISI304}}, T = T) \text{ Poisson's Ratio for 304 Stainless}$$

Upper Bound Calculation for the Critical Pressure to buckle the neck. Assumes very stiff support at each end of the cylindrical nec

$$P_{cr,UB} = \frac{2.42 \cdot E \cdot \left[\frac{t_w}{D} \right]^{2.5}}{(1 - \nu^2)^{0.75} \cdot \left[\frac{L}{D} - 0.477 \cdot \left[\frac{t_w}{D} \right]^{0.5} \right]}$$

$$P_{cr,UB,E} = P_{cr,UB} \cdot \left| 145038 \cdot \frac{\text{psi}}{\text{GPa}} \right| \text{ Upper bound for critical pressure in psi}$$

SOLUTION

Unit Settings: SI K Pa J mass deg

$$D = 0.635 \text{ [m]}$$

$$\nu = 0.29$$

$$R = 0.3175 \text{ [m]}$$

$$E = 199.8 \text{ [GPa]}$$

$$P_{cr,UB} = 0.00004339 \text{ [GPa]}$$

$$T = 290 \text{ [K]}$$

$$L = 0.2032 \text{ [m]}$$

$$P_{cr,UB,E} = 6.294 \text{ [psi]}$$

$$t_w = 0.0005842 \text{ [m]}$$

No unit problems were detected.

KEY VARIABLES

$$P_{cr,UB,E} = 6.294 \text{ [ps]} \text{ Upper Bound for Pressure to Buckle the Inner Wall Neck}$$

Buckling Calculations for Inner Main Wall of MVE 808 Freezer

$$D = 28.3125 \text{ [in]} \cdot \left| 0.0254 \cdot \frac{\text{m}}{\text{in}} \right| \text{ Diameter of inner main wall}$$

$$L = 20 \text{ [in]} \cdot \left| 0.0254 \cdot \frac{\text{m}}{\text{in}} \right| \text{ Length of cylindrical main wall}$$

$$t_w = 0.038 \text{ [in]} \cdot \left| 0.0254 \cdot \frac{\text{m}}{\text{in}} \right| \text{ Wall Thickness}$$

$$R = \frac{D}{2} \text{ Radius is 1/2 Diameter}$$

$$T = 290 \text{ [K]}$$

$$E = \text{YoungsModulus} (\text{Stainless}_{\text{AISI304}}, T = T) \text{ Young's Modulus for 304 Stainless}$$

$$\nu = \text{PoissonsRatio} (\text{Stainless}_{\text{AISI304}}, T = T) \text{ Poisson's Ratio for 304 Stainless}$$

Upper Bound Calculation for the Critical Pressure to buckle the main wall. Assumes very stiff support at each end of the cylindrical wall

$$P_{cr,UB} = \frac{2.42 \cdot E \cdot \left[\frac{t_w}{D} \right]^{2.5}}{\left(1 - \nu^2 \right)^{0.75} \cdot \left[\frac{L}{D} - 0.477 \cdot \left[\frac{t_w}{D} \right]^{0.5} \right]}$$

$$P_{cr,UB,E} = P_{cr,UB} \cdot \left| 145038 \cdot \frac{\text{psi}}{\text{GPa}} \right| \text{ Upper bound for critical pressure in psi}$$

SOLUTION**Unit Settings: SI K Pa J mass deg**

$$D = 0.7191 \text{ [m]}$$

$$E = 199.8 \text{ [GPa]}$$

$$L = 0.508 \text{ [m]}$$

$$\nu = 0.29$$

$$P_{cr,UB} = 0.00004947 \text{ [GPa]}$$

$$P_{cr,UB,E} = 7.175 \text{ [psi]}$$

$$R = 0.3596 \text{ [m]}$$

$$T = 290 \text{ [K]}$$

$$t_w = 0.0009652 \text{ [m]}$$

No unit problems were detected.

KEY VARIABLES

$$P_{cr,UB,E} = 7.175 \text{ [psi]} \text{ Upper Bound for Pressure to Buckle the Main Inner Wall}$$